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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,877	09/18/2000	Song-Bae Kim	PM271427	3124

900 7500 12/02/2002

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EXAMINER

COE, SUSAN D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 12/02/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,877

Applicant(s)

KIM, SONG-BAE

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed September 23, 2002, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 9-12 have been added.
3. Claims 1-12 are pending.

Claim Rejections - 35 USC § 112

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is indefinite because at the beginning of the claim it states that the composition can contain either Pulsatillae radix or Ulmaceae radix (lines 3-5). Then the claim states that both ingredients must be present in amounts "greater than 0% (lines 6 and 7)". These limitations conflict; therefore, it is not clear what ingredients must be in the composition in order to meet the claimed limitations. Claim 5 has similar conflicting limitations that make the claim indefinite.
5. Claim 2 is also indefinite for similar reasons. The claim states that the composition contains either Pulsatillae radix or Ulmaceae radix (lines 2 and 3). Then the claim states that both ingredients must be present in amounts "greater than 0%" and that both Pulsatillae radix **and** Ulmaceae cortex are extracted (lines 6-8). In addition, the claim states that either Ginseng radix or Glycyrrhizae radix can be in the composition (line 4). Then the claim states that both must be present (lines 9-11). Claim 6 has similar limitations that make the claim indefinite.

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6. Claim 4 recites the limitation "the auxiliaries" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

7. Claims 1, 2, 9 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,071,521 for the reasons set forth on pages 3 and 4 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claimed composition has unexpected results over US '521 that show that the process steps in the current product-by-process claims should be given patentable weight. US '521 has a composition with the same ingredients but are extracted at a temperature higher than the currently claimed limitation of below 60 degrees C. To support applicant's statement that this lower extraction temperature creates a patentable difference between the composition of US '521 and the claimed composition, applicant points out comparative examples 1-3, examples 1-9, and the experiments in the specification. However, these examples do not show that the current composition functions differently than the composition of US '521. Comparative example 1 is a composition prepared by extracting Pulsatillae radix at a temperature greater than 60 degrees C (see page 6 of the specification). Example 1 is a composition prepared by extracting Pulsatillae radix at a temperature less than 60 degrees C (see page 7 of the specification). The antitumor effects of Comparative example 1 and Example 1 are compared in Experiment 2 (pages 11-12 of the specification). This experiment shows that both of the compositions have the same effects. For

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each group of ten rats injected with the composition Comparative example 1 or Example 1, nine rats were cured by the 15th day and one rat died on the 16th day. Therefore, this experiment does not show unexpected results. Experiment 3 also compares Comparative example 1 and Example 1; however, the results from this Experiment are not a true comparison because the composition of Comparative example 1 had been stored for 6 months while the composition of Example 1 has not been stored (see page 12 of the specification).

Applicant also argues that there is a difference in stability between the claimed composition and the composition of US '521. Applicant states that this is demonstrated on page 18 of the specification. However, the data presented on page 18 is not clear. It is not clear which samples are evaluated in Stability test 1. In addition, the only composition that has specifically been shown to have instability is the composition prepared in Comparative example 2. Since the examples are unclear and only one composition has been specifically examined, this allegation of unexpected results is not properly supported by the specification.

Claim Rejections - 35 USC § 102/103

8. Claims 1-4, 9, and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 416 502 A1 for the reasons set forth on pages 4-6 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the invention of EP '502 is distinct from the current invention for the same reasons as argued for the distinction between this invention and the invention of US '521. Therefore, the response to these arguments are the same as those discussed above in paragraph 7.

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Claim Rejections - 35 USC § 103

9. Claims 5-8, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 416 502 A1 for the reasons set forth on pages 6 and 7 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the invention of EP '502 is distinct from the current invention for the same reasons as argued for the distinction between this invention and the invention of US '521. Therefore, the response to these arguments are the same as those discussed above in paragraph 7.

10. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
November 29, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER